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Pulmonary physician, former FDA Medical Reviewer, pharmaceutical and device regulatory expert, and clinical scientist with over 15 years total experience in patient care, regulatory strategic and tactical operations, and clinical trial design and implementation.

Areas of particular focus include:

- Pulmonary medicine and patient care
- Regulatory strategy for development of respiratory medical devices and drugs
- Planning and implementation of clinical development plans in diverse therapeutic areas including respiratory diseases (asthma, COPD, cystic fibrosis), diabetes, pain management
- Clinical and respiratory physiology research, with academic and clinical faculty appointments
- Top Level Corporate Management expertise

Education & Training

Fellowship	Pulmonary & Critical Care Division, Howard University Hospital, Washington, DC
Fellowship	Chest Department, Papworth Hospital & Addenbrookes Hospital, University of Cambridge, Cambridge, England
Residency	Dept of Medicine, University College Hospital, Ibadan, Nigeria
Internship	General Hospital, Abeokuta, Nigeria
MD	College of Medicine, University of Ibadan, Nigeria

Medical Licensure

State of Maryland

Professional Experience

1997 to date	ARADIGM CORPORATION Vice President, Clinical & Regulatory Affairs
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1991 to 1997	U.S. FOOD AND DRUG ADMINISTRATION (FDA) Medical Reviewer, Division of Pulmonary Drug Products (HFD-570) Center for Drug Evaluation & Research, FDA, Rockville, MD
1987 to 1991	PAPWORTH & ADDENBROOKES HOSPITAL, CAMBRIDGE, UK Clinical & Research Fellow

Recent Awards, Scientific & Academic Appointments

- Industry Representative for the Anesthesiology and Respiratory Therapy Devices Panel, Medical Devices Advisory Committee in FDA's Center for Devices and Radiological Health (CDRH) – 2001 to date
- Asst. Clinical Professor, Pulmonary & Critical Care Medicine, School of Medicine, University of California, Davis – 1999 to date
- FDA Commendable Service Award, for work on CFC Phaseout –1997
- Outstanding Reviewer Award, CDER, FDA - 1996
- Member of the United Nations Environmental Program (UNEP), Aerosol Technical Options Committee – 1995 to date
- Editorial Reviewer, *Chest* – 1995 to date
- Editorial Board Member, *International Journal for Aerosol Medicine* – 1994 to date
- Merit Award for Exemplary Performance in Drug Regulation, Center for Drug Evaluation and Research, FDA –1994
- Assistant Professor of Medicine, Pulmonary & Critical Care Medicine, Howard University, Hospital Washington, DC – 1992-1997

Membership of Professional Societies

American College of Clinical Pharmacology
 American Diabetes Association
 American Thoracic Society
 British Thoracic Society
 Drug Information Association
 International Pharmaceutical Aerosol Consortium – Regulatory Science
 International Society for Aerosols in Medicine

Selected Public Presentations & Lectures

Speaker on “Modalities for Insulin Therapy: Pulmonary Route for Delivery of Insulin,” *at the Diabetes Symposium, University of the Pacific (UOP), Stockton, CA; November 26, 2001.*

Speaker on “Common Assessments in Respiratory Drug Development – Pulmonary Drug Delivery,” *at PERI’s Respiratory Clinical Development Training Course, Washington, DC; June 5, 2001.*

Speaker on “Emerging Technologies for Disease Management: A Crucial Component in eHealth Education, Compliance and Delivery,” *at the eHealth Initiative’s Policy Conference, San Diego, CA; May 23, 2001.*

Speaker on “New Inhalational (Non Ozone-Depleting) Devices,” *at the AAAAI 57th Annual Meeting, New Orleans, LA; March 19, 2001.*

Speaker on “Maximizing the Relationship Between the Investigator Site and the Study Sponsor,” *at the IIR Conference: Clinical Trial Strategies for Medical Devices & Diagnostics, San Diego, CA; September 25-27, 2000.*

Panelist/speaker for conference on *Clinical Trials: The Next Phase, San Francisco, CA; September 22, 2000.*

Speaker on “A Novel Electronic Inhaler for Delivery of Insulin via the Lung,” *at the IIR Conference: New Technologies and Developments in Non-Invasive Delivery Techniques for Diabetes, McLean, VA; September 11-13, 2000.*

Speaker on “Negotiating Through the Early Phase of Clinical Development of a Novel Technology: A Case Study of a Pulmonary Drug Delivery System,” *at a Scientific Workshop on Clinical Program Design for the New Millennium, San Diego, CA, October 18, 1999.*

Speaker on “Establishing Clinical Feasibility for Pulmonary Drug Delivery for Systemic Drugs,” *at the IIR conference: Clinical Trials for Drug Delivery Systems, San Francisco, CA; July 26-27, 1999.*

Speaker on “Approaches to Clinical Bioequivalence Testing of Inhaled Drugs,” *at the Henry Stewart Conference: Understanding Equivalence Testing for Inhaled Drugs, Rockville, MD, November 23-24, 1998.*

Speaker on “Clinical & Regulatory Aspects of Asthma Management,” *at an American Lung Association seminar on Respiratory Issues Today & Tomorrow, Miami Lakes, FL, May 14, 1998.*

Speaker on “The United States’ CFC-Phaseout Strategy,” *at the meeting of UNEP Aerosol Committee meeting, Mexico City, Mexico; March 9-12, 1997.*

Invited Grand Seminar Speaker on “CFC Phaseout: The FDA Position,” *at the American Academy of Asthma, Allergy & Immunology (AAAAI) annual conference, San Francisco, CA; February 22-25, 1997.*

Speaker on “Clinical Issues Regarding Dry Powder Inhalers,” *at the DIA Conference: Dry Powder Inhalers: Theory into Practice, Washington, DC; January 13-14, 1997.*

Invited Plenary Session Speaker on “CFCs and Aerosol Delivery Systems: FDA’s Point of View,” *at the American College of Allergy, Asthma and Immunology Annual Meeting, Boston, Massachusetts; November 13-18, 1996.*

Invited Speaker on “Implementation of a Transition Policy for CFC MDIs: FDA Role in Transition Policy,” *at the International Conference on Ozone Protection Technologies, Washington, DC; October 21-23, 1996.*

Invited Speaker on “Changing Devices During Aerosol Drug Development,” *at Respiratory Drug Delivery V meeting, Phoenix, Arizona; April 28-May 2, 1996.*

Lecturer on “Regulatory Guidance in Alternative Aerosol Delivery,” *at the Respiratory Care Clinical Training Course organized by the Pharmaceutical Education Research Institute, Annapolis, Maryland; April 14-17, 1996.*

Co-chair and Speaker on “Aerosol Delivery Systems,” *organized by the International Society for Aerosol in Medicine, Hamilton, Ontario, Canada; May 15-19, 1995.*

Presentation on “Study Designs for Inhalational Drug Products,” *at the FDA's Pulmonary-Allergy Advisory Committee meeting, Rockville, Maryland; July 14, 1994. Proceedings reported in the F-D-C Reports, Vol 56, No 29, pgs T&G 4-5.*

Co-chair and Speaker on “Practical Applications of New Asthma Medications: Considerations in the Use of Anti-inflammatory Drugs,” *organized by the American Academy of Allergy and Immunology, Anaheim, California; March 4-9, 1994.*

Co-chair workshop on “MDIs in the New Millennium,” Session Title: Safety Concerns with MDIs, *Drug Information Association (DIA), Toronto, Canada; October 18-19, 1993.*

“Clinical Lung Transplantation: An Overview” *at the Center for Drug Evaluation and Research, FDA, Staff College, Rockville, Maryland; April 23, 1993.*

Discussion Panel member on Aerosols in Medicine, *9th Congress of the International Society for*

Aerosols in Medicine, Garmisch, Germany; March 30-April 3, 1993.

Speaker on “How do we assess Bronchial Inflammation and Immunopharmacologic interventions in Asthma,” *organized by the American Academy of Allergy and Immunology, Chicago, Illinois; March 12-17, 1993.*

Speaker on Standards for In Vitro/In Vivo measurements in MDI, *organized by the International Society for Aerosols in Medicine, Atlanta, Georgia; November 20-22, 1992.*

Publications

Books and theses:

“Delivery of Biologics to the Lung.” Cipolla D, Farr S, Gonda I, Otulana BA. *Prog Respir Res.* Volume 31, pages 20-23. 2001.

“Central and Peripheral Respiratory Control mechanisms after Lung Denervation in humans”. Otulana BA, Higenbottam T. In: *Ventral Brainstem Mechanisms and Control of Respiration and Blood Pressure.* Chapter 13, pages 225-236. CO Truth et. al. (Editors). Marcel Dekker Inc., New York: May 1995.

The Pathophysiology of Respiratory Gas Exchange. Otulana BA, 1992

Bronchial Provocation Challenge in Asthma: The role of Physical Exercise and Cold air. Otulana BA, 1989

Journal articles:

Otulana BA, Thippawong J. Systemic delivery of small molecules: product development issues focused on pain therapeutics. *Respiratory Drug Delivery VIII, Tucson, AZ, May 2002*

Sangwan S, Agosti J, Bauer L, Otulana B, Morishige R, Cipolla D, Blanchard J, Smaldone G. Aerosolized Protein Delivery in Asthma: Gamma Camera Analysis of Regional Deposition and Perfusion. *Journal of Aerosol Medicine* 2001; 14(2):185-195

Takao M, Higenbottam TW, Audley T, Otulana BA, Wallwork J. Effects of inhaled nebulized steroids (budesonide) on acute and chronic lung function in heart-lung transplant patients. *Transplant Proc.* 1995; 27(1):1284-5

Clelland C, Higenbottam T, Stewart S, Otulana B, Wreghitt T, Gray J, Scott J, Wallwork J. Bronchoalveolar lavage and transbronchial lung biopsy during acute rejection and infection in heart-lung transplant patients. Studies of cell counts, lymphocyte phenotypes, and expression of HLA-DR and interleukin-2 receptor. *Am Rev Respir Dis* 1993; 147:1386-92

Otulana BA, Varma N, Bullock A, Higenbottam TW. High dose nebulized steroid in the treatment of chronic steroid-dependent asthma. *Respiratory Medicine* 1992; 86:105-108

Otulana BA, Higenbottam TW, Wallwork J. Causes of Exercise Limitation following Heart-Lung Transplantation. *J Heart Transplant* 1992; 11:S244-51

Scott JP, Otulana BA, Mullins PA, Aravot DJ, Higenbottam T, Wallwork J. Late pulmonary haemodynamic changes in heart-lung transplantation. *Eur Heart J* 1992; 13(4):503-507

Scott JP, Sharples L, Mullins P, Aravot DJ, Stewart S, Otulana BA, Higenbottam TW, Wallwork J. Further studies on the natural history of obliterative bronchiolitis following heart-lung transplantation. *Transplant Proc* 1991; 23:1201-2

Higenbottam TW, Otulana BA, Wallwork J. The Physiology of Heart-lung Transplantation in Humans. *News in Physiological Sciences (NIPS)* 1990; 5:71-74

Higenbottam T, Otulana BA, Wallwork J. Transplantation of the lung. *Eur Respir J* 1990; 3(5):594-605

Otulana BA, Higenbottam TW, Scott JP, Wallwork J. A possible role for mixed venous blood changes in the hyperventilation of exercise in heart-lung transplant recipients. *Chest* 1990; 97(3) Suppl.; 88s-89s

Otulana BA, Higenbottam T, Ferrari L, Scott J, Igboaka G, Wallwork J. The Use of Home Spirometry in detecting acute lung Rejection and infection following heart-lung transplantation. *Chest* 1990; 97:353-357

Clelland CA, Higenbottam TW, Otulana BA, Stewart S, Scott JP, McGoldrick JM, Wallwork J. Histological Grading of Acute Lung Rejection on Transbronchial Biopsy helps predict long-term outcome of heart-lung transplants. *Transplant Proc* 1990; 22:116

Awotedu AA, Otulana BA, Ukoli CO. Giant lymph node hyperplasia of the lung (Castleman's disease) associated with recurrent pleural effusion. *Thorax* 1990; 45:775-776

Clelland C, Higenbottam T, Otulana B, Stewart S, Scott J, Wallwork J. Histologic prognostic indicators for the lung allografts of heart-lung transplants. *J Heart Transplant* 1990; 9:177-86

Otulana BA, Higenbottam T, Scott J, Clelland C, Igboaka G, Wallwork J. Lung function associated with histologically diagnosed acute lung rejection and pulmonary infection in heart-lung transplant patients. *Am Rev Respir Dis* 1990; 142:329-332

Otulana B, Higenbottam T. Peak flow and asthma monitoring. *Chemist and Druggist* October 6, 1990:627-628

Scott JP, Higenbottam TW, Clelland CA, Stewart S, Smyth RL, McGoldrick JP, Otulana BA, Wallwork J. Natural history of Chronic Rejection in Heart-lung Transplant Recipients. *J Heart Transplant* 1990; 9: 510-515

Scott JP, Higenbottam T, Clelland C, Hutter J, Stewart S, Otulana BA, Wallwork J. The natural history of Obliterative Bronchiolitis and Occlusive Vascular Disease of patients following heart-lung transplantation. *Transplant Proc.* 1989; 21(1):2592-2593

Otulana BA, Mist BA, Scott JP, Wallwork J, Higenbottam T. The effect of recipient lung size on lung physiology after heart-lung transplantation. *Transplantation* 1989; 48(4):625-629

Otulana BA, Higenbottam TW, Scott JP, Clelland A, Hutter JA, Wallwork J Pulmonary Function monitoring allows diagnosis of Lung Rejection in Heart-Lung Transplant Recipients. *Transplant Proc* 1989; 21(1):2583-2584

Otulana B, Higenbottam T. The Role of Physiological Deadspace and Shunt in the gas exchange of patients with Pulmonary Hypertension: a study of exercise and Prostacyclin infusion. *Eur Respir J* 1988; 1:732-737

Atoba MA, Otulana BA, Adebajo AO. Primary Liver Cell Carcinoma associated with infective liver diseases. *Trop Geogr Med* 1988; 40:244-246

Selected Abstracts (most recent):

Thippawong J, Babul N, Morishige R, Otulana B, Findlay H, Reber K, Milward G, Sharif S. Single Dose Analgesic Efficacy of Inhaled Morphine Delivered via the AERx Morphine Pain Management System after Orthopedic Surgery. *The Journal of Pain, Vol. 3, No. 2(1), April 2002.*

Thippawong J, Babul N, Morishige R, Otulana B, Findlay H, Reber K, Milward G, Sharif S. Multi Dose Analgesic Efficacy of Inhaled Morphine Delivered via the AERx Pain Management System for Outpatient Orthopedic Surgery. *The Journal of Pain, Vol. 3, No. 2(1), April 2002.*

Slatkin N, Rauck R, Koczwara B, Chevlen E, Thippawong J, Morishige R, Otulana B, Beckman R, Gonda I. Analgesic Efficacy of Inhaled Morphine Delivered with the AERx mPMS for Breakthrough Cancer Pain. *The Journal of Pain, Vol. 3, No. 2(1), April 2002.*

McElduff A, Clauson P, Mather LE, Okikawa J, Farr S, Otulana, BA, Thippawong J. The Pharmacokinetics and Pharmacodynamics of a Single Versus Divided Dose of Inhaled Insulin via the AERx Insulin Diabetes Management System. *Diabetes Technology Meeting, San Francisco, CA, November 2001.*

Okikawa J, Rubin J, Linn L, Farr S, Otulana BA, Thippawong J. Using the AERx iDMS Electronic Monitoring Tools to Optimize Diabetic Patient Management. *Diabetes Technology Meeting, San Francisco, CA, November 2001.*

Boyle F, Mather LE, Lam J, Morishige RJ, Otulana BA, Dayton F, Rubsamen RM, Thippawong JB. Inhaled Fentanyl via the AERx System for the Treatment of Breakthrough Cancer Pain. *American Pain Society, 19th Annual Scientific Meeting, Atlanta, GA, November 2000.*

Mather LE, Kam PC, Morishige RJ, Otulana BA, Dayton F, Rubsamen RM. Pharmacokinetics of Orally Inhaled Fentanyl in Healthy Subjects. *American College of Clinical Pharmacology, 29th Annual Meeting, Chicago, IL, September 2000.*

Otulana BA, Morishige RJ, Beckman RA, Johansson ET, Okikawa JK, Fiore MD, Rubsamen RM. Oral Inhalation System for Delivery of Morphine Produces an IV-Like PK Profile. *IASP 9th World Congress on Pain, August 1999.*

Kipnes M, Otulana B, Clauson P, Fischer J, Farr S, Hatorp V, Schwartz S. A Comparison of the Pharmacodynamic Effects of Inhaled Insulin versus Subcutaneous Insulin in Type 1 Diabetic Patients. *American Diabetes Association, 59th Scientific Sessions, San Antonio, TX, June 1999.*